DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 11, 2015

Well Brain International, Ltd.
Victor K. Wai
Managing Director
Room 03, 14/F, Fook Yip Bldg.
53-57 Kwai Fung Crescent
Kwai Chung, N. T. Hong Kong, China

Re: K142055
Trade/Device Name: GYMFORM® ABS&CORE, Model: VDPGYCSET0042
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: NGX
Dated: April 3, 2015
Received: April 10, 2015

Dear Mr. Wai,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Felipe Aguel -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K142055

Device Name
GYMFORM® ABS&CORE, Model: VDPGYCSET0042

Indications for Use *(Describe)*
GYMFORM®ABS& CORE is intended to stimulate healthy muscles in order to improve or facilitate muscle performance. The ABS& CORE may be considered a technique or method for muscle training. 2-area belt is intended for use on the muscles in abdomen or lower back separately. Mini belt is intended for use on the muscles in arms, legs, thighs or buttocks areas separately.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

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## Chapter 5. 510(k) Summary

# 510(k) Summary

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92.

**1. Date of the summary prepared: May 8, 2015**

**2. Submitter's Information**

- 510(k) Owner's Name: Well Brain International Ltd.
- Establishment Registration Number: 3004950644
- Address: Room 03, 14/F, Fook Yip Bldg., 53-57 Kwai Fung Crescent, Kwai Chung, N. T. Hong Kong, China
- Phone: (852) 2619-0833
- Fax: (852) 2429-0960
- Contact Person: Victor K Wai
- Email: victor@wellbrain-intl.com

**3. Subject Device Information**

- Trade Name: GYMFORM®ABS & CORE, Model: VDPGYCSET0042
- Common Name: Powered muscle stimulator
- Classification name: Stimulator, Muscle, Powered, For muscle conditioning
- Review Panel: Physical Medicine
- Product Code: NGX
- Regulation Class: II
- Regulation Number: 890.5850

**4. Predicate Device Information**

| **Predicate Device** | **Predicate Device I** | **Predicate Device II** |
|---|---|---|
| **Sponsor** | Well Brain International Ltd. | Contour Technology |

| **Predicate Device** | **Predicate Device I** | **Predicate Device II** |
|---|---|---|
| **Device Name** | Gymform® ABS-A-ROUND, model: VDPGYCIND0016 | Contour Technology Muscle Stimulator |
| **510(k) Number** | K130074 | K111476 |
| **Product Code** | NGX | NGX |
| **Regulation Number** | 21 CFR 890.5850 | 21 CFR 890.5850 |
| **Regulation Class** | II | II |

**5. Device Description**

GYMFORM® ABS&CORE is a two channels battery operated muscle stimulation system specifically designed to stimulation the muscles.

The 2-area belt is intended for use on the muscles in abdomen or lower back separately.

Mini belt is intended for use on the muscles in arms, legs, thighs and buttocks areas separately.

It is comprised of a console for signal generation, two belts (2-area belt and mini belt) for fixation, and electrode pads for signal connection to skin. The electrode pads are replaceable.

Power is derived from 2 “AAA” batteries located in a compartment protected by a removable battery cover.

There is no current passed from side to side. The user cannot access the wiring or connectors within the belt.

The stimulator sends gentle electrical current to targeted muscle group through the electrodes placed on the skin. The parameters of the device are controlled by the buttons. Its intensity level can be adjustable by user.

**6. Intended Use / Indications for Use**

GYMFORM® ABS& CORE is intended to stimulate healthy muscles in order to improve or facilitate muscle performance. The ABS& CORE may be considered a technique or method for muscle training.

2-area belt is intended for use on the muscles in abdomen or lower back separately.

Mini belt is intended for use on the muscles in arms, legs, thighs or buttocks areas separately.

**7. Test Summary**

ABS & CORE has been evaluated the safety and performance by lab bench testing as following:

- Electrical safety test according to IEC 60601-1 and IEC 60601-2-10 standards

- Electromagnetic compatibility test according to IEC 60601-1-2 standard
- Software verification and validation test according to the requirements of the FDA "Guidance for Pre Market Submissions and for Software Contained in Medical Devices"
- Waveform test report to verify the output specifications of the device according to IEC 60601-2-10 and Guidance for Powered Muscle Stimulator.
- Dispersion test and Shelf test according to ASTM F 1980-07, Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devicesand Guidance: Shelf Life of Medical Device.
- Adhesion test according to Section 5.4 of AAMI EC 12_2000_(R) 2010 Disposable ECG electrodes.

## 8. Comparison to predicate device and conclusion

The technological characteristics, features, specifications, materials, mode of operation, and intended use of GYMFORM®ABS & CORE is substantially equivalent to the predicate devices quoted above.
The differences between the subject device and predicate devices do not raise new issues of safety or effectiveness.

| Elements of Comparison | Subject Device | Predicate Device I | Predicate Device II | Remark |
|---|---|---|---|---|
| **Basic Unit Characteristics** | | | | |
| Device Name and Model | GYMFORM® ABS & CORE, Model: VDPGYCSET0042 | Gymform® ABS-A-ROUND, model: VDPGYCIND0016 | Contour Technology Muscle Stimulator | -- |
| 510 (K) Number | Applying | K130074 | K111476 | -- |
| Intended Use | GYMFORM®ABS& CORE is intended to stimulate healthy muscles in order to improve or facilitate muscle performance. The ABS& CORE may be considered a technique or method for muscle training. 2-area belt is | Intended Use / Indications for Use: The GYMFORM®ABS-A-ROUND is intended to stimulate healthy muscles in order to improve or facilitate muscle performance. The ABS-A-ROUND | The Contour Technology Muscle Stimulator is intended to stimulate healthy muscles in order to improve or facilitate muscle performance. The Contour Technology Muscle Stimulator may therefore be considered a | SE |

| Elements of Comparison | | Subject Device | Predicate Device I | Predicate Device II | Remark |
|---|---|---|---|---|---|
| | | intended for use on the muscles in abdomen or lower back separately. Mini belt is intended for use on the muscles in arms, legs, thighs or buttocks areas separately. | may be considered a technique or method for muscle training. The 3-area belt is intended for use on the muscles in abdomen, left waist and right waist alternately. The Mini belt is intended for use on the muscles in arms, legs (lower extremities), thighs and buttocks areas separately. | technique or method for muscle training. The Contour Technology Muscle Stimulator Ab Belt accessory is intended for use on abdominal muscles only for strengthening and toning of abdominal muscles. The Contour Technology Muscle Stimulator BackPad accessory is intended for use on the lower back muscles only. | |
| Stimulated muscles | | Abdomen, lower back, arms, legs, thighs and buttocks | Abdomen, lower back, arms, legs, thighs and buttocks | Abdomen, lower back | SE |
| Power Sources | | 2 x 1.5V AAA batteries | 3 x 1.5V AAA batteries | 4 x 1.5V AAA batteries | SE Note 1 |
| Method of Line Current Isolation | | Battery Supply N/A | Battery Supply N/A | Battery Supply N/A | SE |
| Patient Leakage Current | Normal Condition | 10μA | 5.8μA | -- | SE Note 1 |
| | Single Fault Condition | 50μA | 8.5μA | -- | SE Note 1 |
| Number of Modes | | 6 | 6 | -- | SE |

| **Elements of Comparison** | | **Subject Device** | **Predicate Device I** | **Predicate Device II** | **Remark** |
|---|---|---|---|---|---|
| Number of Channels | | 2 | 3 | -- | SE<br>Note 1 |
| -Synchronous or Alternating | | Alternating | Alternating | -- | SE |
| -Method of Channel Isolation | | Press MODE button for 3 seconds | Press FLR button | -- | SE<br>Note 1 |
| Number Intensity Level | | 31 steps | 99 steps | -- | SE<br>Note 1 |
| Regulated Current or Regulated Voltage | | Regulated Voltage | Regulated Voltage | -- | SE |
| Software/Firmware/Microprocessor control | | Yes | Yes | -- | SE |
| Automatic Overload Trip | | No | No | -- | SE |
| Automatic No-load Trip | | Yes. | Yes | -- | SE |
| Automatic Shut Off | | Yes. | Yes | -- | SE |
| Patient Override Control | | Yes | Yes | -- | SE |
| Indicator Display | On/Off Status | Yes | Yes | -- | SE |
| | Low Battery | Yes | Yes | -- | SE |
| | Voltage/Current Level | Yes | No | -- | SE |
| Timer Range | | Default time is 10 minutes | Default time is 19 minutes | -- | SE<br>Note 1 |
| Console weight | | 50g(Without batteries) | 70g (Without batteries) | -- | SE<br>Note 1 |
| Accessories weight | | Big belt: 150g<br>Small belt: 65g<br>Electrode pad: 15g<br>Carry bag: 60g | 3-area belt: 310g<br>Mini belt: 25g<br>Electrode pad (big): 40g<br>Electrode pad | -- | SE<br>Note 1 |

| Elements of Comparison | Subject Device | Predicate Device I | Predicate Device II | Remark |
|---|---|---|---|---|
| | | (small): 26g | | |
| Console dimensions | 100 mm(L) × 68 mm (W) × 24.5 mm (H) | 91.8 mm(L) × 25.5 mm (W) ×82 mm (H) | -- | SE<br>Note 1 |
| Electrode pad dimension | 40 mm (L) × 70 mm (W) ×3mm (H) | Small: 33.0 cm²<br>Big: 34.5 cm² | 40.5 cm² | SE<br>Note 1 |
| Housing Materials and Construction | Console: ABS plastic<br>Belt: Polyester<br>Electrode pads: Glycerine, Polyacrylic acid, Water and Salt | Console: ABS plastic<br>Belt: Polyester<br>Electrode pads: Glycerine, Polyacrylic acid, Water and Salt | -- | SE |
| **Output Specification** | | | | |
| Waveform | Symmetrical | Symmetrical | -- | SE |
| Shape | Rectangular | Rectangular | -- | SE |
| Maximum Output Voltage($V_{peak-topeak}$) (+/- 10%) | 132V @ 500Ω<br>138V @ 2kΩ<br>140V @ 10kΩ | 108V @ 500Ω<br>124V @ 2kΩ<br>126V @ 10kΩ | -- | SE<br>Note 2 |
| Maximum Current Density($I_{peak-topeak}$) | 264mA @ 500Ω<br>69mA @ 2kΩ<br>14mA @ 10kΩ | 216mA @ 500Ω<br>62mA @ 2kΩ<br>12.6mA @ 10kΩ | -- | SE<br>Note 2 |
| Frequency range | 2 Hz, 10 Hz, 50 Hz, 90 Hz, 120 Hz | 2 Hz, 10 Hz, 50 Hz, 90 Hz, 120 Hz | 1 to 120 Hz | SE<br>Note 2 |
| Pulse width range | 108μs / 124μs | 100 μs / 120 μs | -- | SE<br>Note 2 |

| **Elements of Comparison** | **Subject Device** | **Predicate Device I** | **Predicate Device II** | **Remark** |
|---|---|---|---|---|
| Pulse duration(Only changes with the mode) | Mode 1: 500ms;<br>Mode 2: 11.1ms;<br>Mode 3: 8.3ms;<br>Mode 4:<br>Front 90s: 11.1ms;<br>Back 90s: 8.3ms;<br>Mode 5: 100ms;<br>Mode 6: 20ms | Mode 1: 500ms;<br>Mode 2: 11.1ms;<br>Mode 3: 8.33ms;<br>Mode 4:<br>Front 90s: 11.1ms;<br>Back 90s: 8.33ms;<br>Mode 5: 100ms;<br>Mode 6: 20ms | 340 μs | SE<br>Note 2 |
| Phase duration(Only changes with the mode) | Mode 1: Not applicable(Continuous pulse)<br>Mode 2: 2s<br>Mode 3: 2s<br>Mode 4: 2s<br>Mode 5: 10s<br>Mode 6: 16s | Mode 1: Not applicable(Continuous pulse)<br>Mode 2: 2s<br>Mode 3: 2s<br>Mode 4: 2s<br>Mode 5: 10s<br>Mode 6: 16s | -- | SE |
| Net Charge | 19.2μC@ 500Ω | 15.7μC @ 500Ω | -- | SE<br>Note 2 |
| Maximum Phase Charge | 16.4μC@ 500Ω | 13.0μC@ 500Ω | -- | SE<br>Note 2 |
| Maximum Current Density | 0.082 mA/cm²@ 500Ω | 0.057 mA/cm²@ 500Ω | 0.55 mA/cm² @ 500Ω | SE<br>Note 2 |
| Maximum Power Density | 94.8 μW/cm² @ 500Ω | 53.8 μW/cm² @ 500Ω | -- | SE<br>Note 2 |
| ON time | 0.5s | 1s | -- | SE<br>Note 2 |
| OFF time | 0.5s | 1s | -- | SE<br>Note 2 |
| Contraction and Relaxation time | Adjustable, due to different modes. | Adjustable, due to different modes. | -- | SE |
| **Burst Mode** | | | | |
| Pulse per burst | 1~397 | 1~397 | -- | SE |

| **Elements of Comparison** | **Subject Device** | **Predicate Device I** | **Predicate Device II** | **Remark** |
|---|---|---|---|---|
| Bursts per second | 0.125~1 | 0.125~1 | -- | SE |
| Burst Duration(s) | 1~8 | 1~8 | -- | SE |
| Duty Cycle | 0.02%~1.28% | 0.02%~1.19% | -- | SE<br>Note 2 |
| **Additional Features** | | | | |
| Environment for operating | Temperature: 5 ~ 40° C<br>Humidity: 20 ~65% RH | Temperature: 5 ~ 45° C<br>Humidity: 20 ~65% RH | -- | SE |
| Environment for storage | Temperature: 0 ~40° C<br>Humidity: 10 ~90% RH | Temperature: 5 ~ 45° C<br>Humidity: 20 ~65% RH | -- | SE |
| Biocompatibility | All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements. | All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements. | All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements. | SE |
| Electrical Safety | Comply with IEC 60601-1 and IEC 60601-2-10 | Comply with IEC 60601-1 and IEC 60601-2-10 | Comply with IEC 60601-1 and IEC 60601-2-10 | SE |
| EMC | Comply with IEC 60601-1-2 | Comply with IEC 60601-1-2 | Comply with IEC 60601-1-2 | SE |

**Comparison in Detail(s):**

**Note 1:**

Although the power sources, patient leakage current in normal condition and single fault condition, number of channels, synchronous or alternating, method of channel isolation, number intensity level, timer range console weight, accessories weight, console dimensions, electrode pad dimension of subject device are a

little different from the predicate devices, they are all compliant with requirements of IEC 60601-1, IEC 60601-1-2 and Guidance for Powered Muscle Stimulator. So the differences of the function specifications will not raise any safety or effectiveness issue.

**Note 2:**

Although the maximum output voltage, maximum current density, frequency range, pulse width range, pulse duration, contraction time, net charge, maximum phase charge, maximum current density, maximum power density, on time, off time, contraction time, relaxation time and duty cycle of subject device are a little different from the predicate devices, they are all compliant with the requirements of IEC 60601-1, IEC 60601-2-10, and Guidance for Powered Muscle Stimulator. So the differences of function specification will not raise any safety or effectiveness issue.

**Finial Conclusion:**

The subject device "GYMFORM® ABS& CORE" is Substantial Equivalence to the predicate device.